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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/765,218

01/18/2001

Markus Haller

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7590

07/22/2004

MEDTRONIC, INC.

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EXAMINER

PRIETO, BEATRIZ

ART UNIT

PAPER NUMBER

2142

DATE MAILED: 07/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/765,218

Applicant(s)

HALLER ET AL.

Examiner

Prieto B

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/01 & 12/02
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____



DETAILED ACTION

1. This communication is in response to Application No. 09/765,218 filed 01/18/01, claims 1-33 have been examined.

2. The following informalities are noted in the claims for applicant's consideration. Specifically, claim 1, item (f) read when communication initiated between the communication module and the communication system, ordinarily communication occurs between at least two receiving/transmitting entities, certain uncertainties with respect to the communication system having this characteristic, correction and/or clarification is required. Claim 16, item (d) ending term of the limitation ends with a period. Furthermore, claims 6 & 21, the communication module and implantable medical device (IMD) seem to have drawing reference (100 and 10) numbers being the only where this occurs, it may be a typographical error.

3. The following informality is noted with respect to the specification, specifically, on page 37, and on line 6-7, mobile telephone and communication module are both referred to with the same reference number, i.e. 100, further on line 15, (same page) communication module is referred to as element (10). It is suggested applicant review disclosure in its entirety for further inconsistencies, if any. Correction is required.

Rejection under 35 U.S.C. 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-11, and 13-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over SNELL (US 5,720,771) in view of NAPPOLZ et. al. (US 5,720,770) (Nappholz hereafter) in further view of KROLL et. al. (US 5,258,906).

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Regarding claim 1, Snell teaches features of the claimed invention, teachings the system/method of Figs. 1-4, comprising:

an implantable medical device (IMD) (16) implanted with the body of a patient (col 4/lines 10-15);

the IMD being capable of bi-directional communication with a communication module (10) located outside the patient's body (col 7/lines 16-25, 43-56);

a remote communication system (12 of Fig. 1);

a communication system capable supporting bi-directional communication with the remote computer system (col 5/lines 2-36); however Snell is silent with respect to the use of a mobile telephone in the communication system;

Nappholz teaches a system/method related to medical devices, including a cellular telephone (14 of Fig. 5) (col 2/line 66-col 3/line 9, col 5/lines 20-25) communicatively coupled to a communication module and configured to send and receive information (col 2/lines 46-52 and col 4/lines 6-25) and further communicate with a remote computer system (27) (col 4/lines 6-25) via cellular telephone and a communication system (26) (col 4/lines 6-11); however Snell and Nappholz are silent with respect to generating invoices;

Kroll teaches a system/method related to generating invoice entity usable with medical devices, specifically, an communication device (12 of Fig. 1) comprising invoice generating entity communicatively couple to a medical device (21 of Fig. 1) (col 3/lines 21-49), the invoice generating device configured to generate an invoice (col 3/lines 62-col 4/line 14, col 5/lines 8-15, 43-68), when communication between the medical device is initiated the communication device invoicing entity (col 4/lines 41-63).

It would have been obvious to one ordinary skilled in the art at the time the invention was made given the suggestions of Snell for monitoring an implantable medical device on a patient, the teachings on Nappholz for the same purpose further including the transmission of data obtained from the monitored device over a cellular network, motivation would be to alert patients condition to a health care provider or facility and provide remedial response if required, including corrective therapy, curative, first-aid, etc). Further, given the same suggestions of the Snell reference, the teachings of Kroll for providing a invoice generation mechanism related to services provided by medical devices would be readily apparent, one would be motivated given the mechanism's transmission, self-contained modularity and add-on capability of Kroll's device, further including the transmission of the formatted invoice and the reception of data from a remote location over a model, to generate invoices in the Snell's system for transmission to remote

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locations to base remuneration of services provided based on the actual metered usage of the medical device of the patient.

Regarding claim 2, invoice generation means are incorporated into the communication system, for example communicatively connectable to the medical device for receiving information therein (Kroll: col 3/lines 21-43).

Regarding claim 3, invoice generation means are incorporated into a telephone system included in the communication system (Kroll: col 7/lines 5-16).

Regarding claim 4, system of claim 1, further comprising means for electronically transmitting generated invoices to at least one predetermined location for further processing and billing (Kroll: col 4/lines 7-14).

Regarding claim 5, means (12 of Fig. 1) for calculating the amount of each invoice in accordance with the number, type or frequency of services provided to the patient by the system (Kroll: col 3/line 53-col 4/line 2).

Regarding claim 6, means (12 of Fig. 1) for calculating the amount of each invoice in accordance with the type or identification indicia stored in communication module or IMD (Kroll: col 3/line 53-col 4/line 2).

Regarding claim 7, wherein the remote computer system further comprises means for making a remote diagnostic assessment of the patient's condition on the basis of the information relayed thereto by the IMD or the communication module (Nappholz: col 13/line 47-col 14/line 36).

Regarding claim 8, although Kroll teaches generating an invoice on the basis of the information relayed by the IMD, it does not teach invoice generation in response to a diagnostic assessment;

Official Notice (see MPEP § 2144.03 Reliance on "Well Known" Prior Art) is taken that health care providers and services including health management organization that provide means for quantitatively analyze said providers and services was old and well known in the art. For example and not limited to, the Dang reference (US 5,835,897) discussed as prior art, a medical reimbursement computer system including means (computer implementation) of estimating health care services/consumption through the use of diagnostic and patient's illness data relationships and computing or calculating the

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amount of payment to the health provider. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to include means for generating an invoice based on a statistical diagnostic assessment which minimizes variances, motivation would be to automatically further determine an expected cost of treatment based on obtained diagnostic.

Regarding claim 9, wherein the remote computer system further comprises means for remotely executing a remedial response or therapy on the basis of the information relayed thereto by at least one of the IMD and the communication module (col 13/line 47-col 14/line 36.)

Regarding claim 10, this claim is substantially the same as claim 8, thereby same rationale of rejection is applicable.

Regarding claim 11, wherein the communication module is incorporated into the mobile telephone (Nappholz: 14 of Figs. 3-4, col 3/lines 1-65 and col 5/lines 20-25).

Regarding claim 13, wherein the IMD and the communication module communicate with one another using radio-frequency telemetry (Nappholz: col 4/lines 6-9, Fig. 2 and col 5/lines 15-19 also Snell: see 14 of Fig. 1).

Regarding claim 14, wherein the means for generating an invoice is incorporated into a wireless network (Nappholz: col 7/lines 23-27).

Regarding claim 15, generating automatic invoices in response to a patient-initiated (Kroll: col 4/lines 31-63).

Regarding claim 16, this claim is substantially the same as the combined claims 1, and 11, thereby, same rationale of rejection is applicable.

Regarding claims 17-29, these claims are substantially the same as claims 2-13, 14-15, respectively, same rationale of rejection is applicable.

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Regarding claim 30, this claim (although presented in a "preamble-like" form) is substantially the same as claim 1, same rationale of rejection is applicable.

Regarding claim 31, this claim (although also presented in a "preamble-like" form) seems to be a system claim, substantially the same as the combined claims 1 and/or 11, thereby, same rationale of rejection is applicable.

6. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Snell-Nappholz in view of Kroll in further view of OTSUKA, Ideal state of high density packing view from wiring technology from human brain to LSI and electronic packaging on circuit boards.

Regarding claim 12, however the above-mentioned references do not teach a mobile telephone comprising a PDA.

Otsuka teachings the integration of separate electronic communication components, such as a mobile telephone and a PDA. It would have been obvious to one ordinary skilled in the art at the time the invention was made to further integrate separate application, e.g. PDA to the Nappholz system presently integrating the functionalities of a programmable device and a personal computer application configured for receiving/transmitting telemetry data, with cellular telephone technology, for taking the applied reference teaching a step further, using the advantages of LSI technology and further incorporate a PDA, the size of a card, motivation would be to further provide the patient a more user friendly/portable device that existing prior arts as suggested by the Nappholz reference.

Rejection under 35 U.S.C. 101

7. Claims 32 and 33 are rejected under 35 U.S.C. § 101, which reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 32 and 33 are rejected under 35 U.S.C. §101 because the claimed invention is directed to non-statutory subject matter. In this case, computer-related inventions whether descriptive or functionally descriptive material are non-statutory categories when claimed as descriptive material *per se* (see *Warmerdam*, 33 F.3d at 1360 USPQ2d at 1759), falling under the "process" category (i.e. inventions at that consist of a series of steps or acts to be performed). See 35 U.S.C. 100(b) ("The term process means,

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art, or method, and includes a new of a known process, machine, manufacture, composition of matter or material"). Functional descriptive material: "data structures" representing descriptive material *per se* or computer program representing computer listing *per se* when embodied in a computer-readable media are still not statutory because they are not capable of causing functional change in the computer. However, claimed computer-readable medium encoded with a data structure defined structural and functional interrelationships between the data structure and the computer software and hardware component, which permit the data structure's functionality to be realized, and is thus statutory (see MPEP 2106).

9. Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over NOLAN et. al. U.S. Patent No. 5,404,877 (Nolan hereafter) in view of Kroll.

Regarding claim 32, Nolan teaches substantial features of the invention, including a system (of Fig. 12) further including:

- an implantable medical device (5) (col 3/lines 28-36);

- a remote computer system (220 or 260);

- the implantable medical device capable of sending/receiving communication with a communication module (240) located external to the patient's body to a remote communication system (220/260) (col 23/lines 65-68 and col 24/lines 14-20);

- a cellular/telephonic communicator (240) capable of exchanging information with the communication module (col 23/lines 49-67 and col 24/lines 14-20);

- a communication system (Fig. 12) supporting bi-directional communication with the cellular/telephonic communicator (240) external to the patient's body and the remote computer system (260 or 220) (medical device sending to all, i.e. communicator 240 and remote computers (260 & 220) see col 23/lines 65-68 and sending from computer system to medical device see col 24/lines 14-20);

further including a method comprising:

- the implantable medical device configured to determine that medical attention should be provided to the patient and provide a warning signal based on said determination (col 2/lines 44-56, col 5/lines 56-60, col 6/lines 60-67, and col 9/lines 10-22, 26-31);

- in response to determining that medical attention should be provided sending data from the implantable medical device to the communication module (col 6/lines 60-67, col 9/lines 16-19) for an external remote computer system device;

- remotely analyzing the data (col 24/lines 23-26);

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determining on the basis of the analyzed data whether remedial action respecting the IMD is required (col 24/line 26-30);

remotely executing the determined remedial action via the communication system which supports communication to the IMD or patient therein (col 24/lines 33-38), however Nolan is silent with regards to invoice generation means in his system, and further the claimed functions performed by the communication module and those performed by the mobile telephone are performed by one element, (i.e. 240) in the Nolan reference;

Kroll teaches a system/method related to generating invoice entity usable with medical devices, specifically, an communication device (12 of Fig. 1) comprising invoice generating entity communicatively couple to a medical device (21 of Fig. 1) (col 3/lines 21-49), the invoice generating device configured to generate an invoice (col 3/lines 62-col 4/line 14, col 5/lines 8-15, 43-68), when communication between the medical device is initiated the communication device invoicing entity (col 4/lines 41-63).

It would have been obvious to one ordinary skilled in the art at the time the invention was made given the suggestions of Nolan of a telephonic communicator external to the patient's body, specifically, communicatively coupled to the IMD for sending/sending data thereto, also having mobile phone capabilities for receiving data from the IMD and establishing a telephonic communication with programmable telephone numbers thereby sending messages over a cellular telephone link to remote computer systems. Nolan teaches that these components although not shown individually (microprocessor and sending/receiving circuitry) are also present in the elements 220 and 230. It would be readily apparent to one ordinary skilled in the art that these component are relocatable being either integrated or distributed, e.g. the separation of the telephonic functionalities and the bi-direction communication circuitry would enable multiple patients at home complex building facility each having telephonic functionality components communicate remotely with their individual health care provider's office via one bi-directional communication circuitry. Furthermore, it would have been obvious to one ordinary skilled in the art at the time the invention was made given the suggestions of Nolan for monitoring an implantable medical device on a patient, the teachings on Kroll for providing monetary reimbursement for medical services provided, including invoice generation mechanism would be readily apparent, one would be motivated given the mechanism's transmission, self-contained modularity and add-on capability of Kroll's device, further including the transmission of the formatted invoice and the reception of data from a remote location over a model, to generate invoices in the primary reference's

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system for transmission to remote locations to base remuneration of services provided based on the actual metered usage of the medical device of the patient.

Regarding claim 33, this method claim is substantially the same as claim 32, thereby, same rationale of rejection is applicable.

Pertinent Prior Art:

10. The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Pertinence is presented in accordance with MPEP§ 707.05.

US 5,835,897 (11-1998)

DANG discusses as prior art, the Mohlenbrock, et al. patent, (US 5,018,067, 1991), which discloses an apparatus and method for improved estimation of health resource consumption through the use of diagnostic and/or procedure grouping and severity of illness indicators. This system is a computer-implemented program that calculates the amount of payment to the health provider.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prieto, B. whose telephone number is (703) 305-0750. The Examiner can normally be reached on Monday-Friday from 6:00 to 3:30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's Supervisor, Jack B. Harvey can be reached on (703) 305-9705. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3800/4700.

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Any response to this action should be mailed to:

Commissioner of Patents and Trademarks
Washington, D.C. 20231

or faxed to the Central Fax Office:

(703) 872-9306, for Official communications and entry;

Or Telephone:

(703) 306-5631 for TC 2100 Customer Service Office.

Hand-delivered responses should be brought to Crystal Park II, 2121 Crystal Drive, Arlington
VA, Fourth Floor (Receptionist), further ensuring that a receipt is provided stamped "TC 2100".



B. Prieto
TC 2100
Patent Examiner
July 18, 2004